DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

April 2, 2015

Prismatik Dentalcraft, Inc.
Mr. Brandon Shepard
Regulatory Affairs & Quality Assurance Specialist
2212 Dupont Drive, Suite P
Irvine, California 92612

Re: K143353
Trade/Device Name: Hahn Tapered Implant System
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: II
Product Code: DZE
Dated: March 2, 2015
Received: March 3, 2015

Dear Mr. Shepard:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply

with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,


for Erin I. Keith, M.S.
Division Director
Division of Anesthesiology,
General Hospital, Respiratory, Infection
Control, and Dental Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

# 004 Indications for Use Statement

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

## Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
*See PRA Statement below.*

510(k) Number *(if known)* K143353

Device Name
Hahn Tapered Implant System

Indications for Use *(Describe)*
Hahn Implants are indicated for use in maxillary and mandibular partially or fully edentulous cases, to support single, multiple-unit, and overdenture restorations. The implants are to be used for immediate loading only in the presence of primary stability and appropriate occlusal loading.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

**PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.**

**FOR FDA USE ONLY**

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

This section applies only to requirements of the Paperwork Reduction Act of 1995.

***DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.***

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Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
*PRAStaff@fda.hhs.gov*

*"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."*

# 005 510(k) Summary

[As Required by 21 CFR 807.92]

This 510(k) summary of substantial equivalence information is being submitted in accordance with the requirements 21 CFR 807.92.

## A. SUBMITTER INFORMATION

| | |
|---|---|
| **Company Name**: | PRISMATIK DENTALCRAFT, INC. |
| **Company Address**: | 2212 Dupont Dr., Suite P<br>Irvine, CA 92612 |
| **Company Phone / Fax**: | (949) 225-1269 / (978) 313-0850 |
| **Contact Person**: | **Primary Contact:**<br>Brandon Shepard, (949) 225-1243<br><br>**Secondary Contact:**<br>Marilyn Pourazar, (949) 225-1269 |
| **Date Summary Prepared**: | March 2, 2015 |

## B. DEVICE IDENTIFICATION

| | |
|---|---|
| **Trade/Proprietary Name**: | Hahn Tapered Implant System. |
| **Common Name**: | Endosseous Dental Implant System |
| **Regulation Number**: | 872.3640 |
| **Product Code**: | DZE |
| **Device Class**: | 2 |
| **Review Panel**: | Dental |

## C. IDENTIFICATION OF PREDICATE DEVICE

Trade/Proprietary Name:
Inclusive Tapered Implant System (K121406)

## D. DEVICE DESCRIPTION

The Hahn Tapered Implant System consists of dental implants, abutments, screws, and surgical instruments.They are manufactured from Titanium alloy, grade 23. The implant is designed with an internal hex connection and a tapered body to replace one or more missing teeth. The surface is blasted with Hydroxyl Apatite and acid etched to facilitate osseointegration. The Implants are design with two (2) platform connection geometries; they are available in the following diameters: 3.0mm, 3.5mm, 4. 3mm, 5.0mm, and 7. 0mm diameter is available in the following lengths: 8mm, 10mm, 11.5mm, 13mm, and 16mm. The dental implants are provided sterile (gamma radiation).

## E. INDICATIONS FOR USE

Hahn Implants are indicated for use in maxillary and mandibular partially or fully edentulous cases, to support single, multiple-unit, and overdenture restorations. The implants are to be used for immediate loading only in the presence of primary stability and appropriate occlusal loading.

## F. NON-CLINICAL TESTING

Non-clinical test data was used to evaluate the device's performance, and determine substantial equivalence with predicate devices.

Non-clinical testing was performed in accordance with FDA Guidance "*Class II Special Controls Guidance Document: Root-form Endosseous Dental Implants and Endosseous Dental Implant Abutments*" and it consisted of Reliability Calculation, Fatigue Testing and Static Load Failure Testing of finished assembled implant/abutment systems.

The testing performed established that the predicate device is as safe, as effective, and performs as well as the predicate device(s).

## G. SUBSTANTIAL EQUIVALENCE STATEMENT

The proposed device is substantially equivalent with the predicate (K121406) in regards to intended use, materials, design, and performance. In conclusion, the testing and evaluations conducted demonstrate that Hahn Tapered Implant System performs as well as the predicate device.

*(See Comparison Tables below).*

## Comparison of Predicate and Proposed Devices

| Attributes | Predicate Device | Proposed Device | Similarities / Differences |
|---|---|---|---|
| Device Name | **Inclusive Tapered Implant System (K121406)** | **Hahn Tapered Implant System** | |
| Indications for Use | Inclusive Tapered Implants are indicated for use in maxillary and mandibular partially or fully edentulous cases, to support single, multiple-unit, and overdenture restorations. The implants are to be used for immediate loading only in the presence of primary stability and appropriate occlusal loading. | Hahn Implants are indicated for use in maxillary and mandibular partially or fully edentulous cases, to support single, multiple-unit, and overdenture restorations. The implants are to be used for immediate loading only in the presence of primary stability and appropriate occlusal loading. | Same |
| Surface | Blasted with Hydroxyl Apatite | Blasted with Hydroxyl Apatite | Same |
| Connection | Internal Hex | Internal Hex | Same |
| Design | Threaded root-form implant | Threaded root-form implant | Same |
| Implant Body Geometry | Screw Type | Screw Type | Same |
| Diameters (mm) | 3.7, 4.7, 5.2 | 3.0, 3.5, 4.3, 5.0, and 7.0 | Additional Sizes |
| Lengths (mm) | 8, 10, 11.5, 13, and 16 | 8, 10, 11.5, 13, and 16 | Same |
| Sterility | Packaged Sterile | Packaged Sterile | Same |
| Material | Titanium Alloy, Grade 23 | Titanium Alloy, Grade 23 | Same |
| Abutment Angle | 0º-20º | 0º-30º | Increased Angulation Range |
| Abutment Seat | Sits on a taper | Sits on a taper | Same |
| Screw Seat | Sits on a flat | Sits on a taper | Tapered vs. Flat |
| Anatomical Site | Oral Cavity | Oral Cavity | Same |
| Construction | Machined | Machined | Same |
| Conclusion | All differences between the predicate and proposed devices have been evaluated per the testing described in section F (*non-clinical testing*) and the proposed device has performed as well as the predicate; the devices are substantially equivalent. | | |